

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2013-0399; FRL-9393-4]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 53 chemical substances which were the subject of premanufacture notices (PMNs). Seven of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture or process any of these 53 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This rule is effective on [insert date 60 days after date of publication in the **Federal Register**]. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on [insert date 14 days after date of publication in the **Federal Register**].

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before [insert date 30 days after date of publication in the Federal Register] (see Unit VI. of the SUPPLEMENTARY INFORMATION). If EPA receives written adverse or critical

comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [insert date 30 days after date of publication in the Federal Register], EPA will withdraw the relevant sections of this direct final rule before its effective date.

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0399, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments.
- Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA-HQ-OPPT-2013-0399. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2013-0399. EPA's policy is that all comments received will be included in the docket without change and may be made available at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be

Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at http://www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at http://www.regulations.gov, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-

1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR, are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

- B. What Should I Consider as I Prepare My Comments for EPA?
- 1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
 - 2. Tips for preparing your comments. When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
 - vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it

occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA

section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 53 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 53 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for nonconfidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, for TSCA non-section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
 - CFR citation assigned in the regulatory text section of this rule.

This rule includes PMN substances, P-09-198 and P-09-199, whose reported chemical names include the term "carbon nanotube" or "CNT". Because of a lack of established nomenclature for carbon nanotubes, the TSCA Inventory names for carbon nanotubes are currently in generic form, e.g., carbon nanotube (CNT), multi-walled carbon nanotube (MWCNT), double-walled carbon nanotube (DWCNT), or single-walled carbon nanotube (SWCNT). EPA uses the specific structural characteristics provided by the PMN submitter to more specifically characterize the Inventory listing for an individual CNT. All submitters of new chemical notices for CNTs in this SNUR have

claimed those specific structural characteristics as CBI. EPA is publishing the generic chemical name along with the PMN number to identify that a distinct chemical substance was the subject of the PMN without revealing the confidential chemical identity of the PMN substance. Confidentiality claims preclude a more detailed description of the identity of these CNTs. If an intended manufacturer or processor of CNTs is unsure of whether its CNTs are subject to this SNUR or any other SNUR, the company can either contact EPA or obtain a written determination from EPA pursuant to the bona fide procedures at § 721.11. EPA is using the specific structural characteristics, for all CNTs submitted as new chemical substances under TSCA, to help develop standard nomenclature for placing these chemical substances on the TSCA Inventory. EPA has compiled a generic list of those structural characteristics entitled "Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature." A copy of this list is available in the docket for these SNURs under docket ID number EPA-HQ-OPPT-2013-0399. If EPA develops a more specific generic chemical name for these materials, that name will be made publicly available.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture volume) and other uses designated in this rule may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes 7 PMN substances (P-09-198, P-09-199, P-09-447, P-09-448, P-12-539, P-13-107, and P-13-109) that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the

PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called "5(e) SNURs" on these PMN substances are promulgated pursuant to § 721.160 and are based on and consistent with the provisions in the underlying consent orders. The 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

In addition, this rule includes SNURs on 3 PMN substances (P-12-539, P-13-107, and P-13-109) that are subject to "exposure-based" consent orders under TSCA section 5(e)(1)(A)(ii)(II), wherein EPA determined that the PMN substances are expected to be produced in substantial quantities, and that there may either be significant or substantial human exposure and/or the PMN substance may enter the environment in substantial quantities. The TSCA section 5(e) consent orders require submission of certain test data to EPA before the manufacturer may exceed a specified production volume. These SNURs designate as a "significant new use" the absence of the protective measures or exceedance of the production volume limit required in the TSCA section 5(e) consent orders.

This rule also includes SNURs on 46 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a "significant new use." These so-called "non-section 5(e) SNURs" are promulgated

pursuant to § 721.170. EPA has determined that every activity designated as a "significant new use" in all non-section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, "(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified" for the PMN substance.

PMN Numbers P-09-198 and P-09-199

Chemical names: Multi-walled carbon nanotubes (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) consent order: June 4, 2010.

Basis for TSCA section 5(e) consent order: The consolidated PMN states that the generic (non-confidential) use of the substances will be as additives for reinforcement. Based on test data on analogous respirable, poorly soluble particulates and other CNTs, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. Further, available data suggests that pulmonary deposition of some nanoparticles, including CNT may induce cardiovascular toxicity if inhaled. The order was issued under section 5(e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that these substances may present an unreasonable risk of injury to human health. To protect against this risk, the consent order requires:

1. Use of personal protective equipment including gloves and protective clothing impervious to the substances when there is potential dermal exposure and a National

Institute of Occupational Safety and Health (NIOSH)-certified full-face respirator with

N-100 cartridges when there is potential inhalation exposure.

2. No domestic manufacture.

3. Use of the substances only as described in the consent order.

4. No use of the substances resulting in surface water releases during processing

and use.

Recommended testing: EPA has determined that the following tests would help

characterize possible effects of the PMN substances. The PMN submitter has agreed not

to exceed a specified production/time limit without performing a 90-day inhalation

toxicity test (OPPTS Test Guideline 870.3465) in rats with a post exposure observation

period of up to 3 months, bronchoalveolar lavage fluid (BALF) analysis, a determination

of cardiovascular toxicity (clinically-based blood/plasma protein analyses),

histopathology of the heart, and certain physical/chemical data.

CFR citation: 40 CFR 721.10671.

PMN Numbers P-09-447 and P-09-448

Chemical name: Sodium olefin sulfonate derivative (generic).

CAS number: Not available.

Effective date of TSCA section 5(e) consent order: February 15, 2013.

Basis for TSCA section 5(e) consent order: The PMNs state that the generic (non-

confidential) use of the substances will be enhanced oil recovery applications. Based on a

CBI analog, EPA predicts toxicity to aquatic organisms may occur at concentrations that

exceed 10 parts per billion (ppb) of the aggregate of these PMN substances in surface

waters. The consent order was issued under TSCA sections 5(e)(1)(A)(i) and

5(e)(1)(A)(ii)(I) based on a finding that uncontrolled manufacture, processing, distribution in commerce, use, and disposal of these substances may present an unreasonable risk of injury to the environment. To protect against these risks, the consent order requires:

- 1. Establishment and use of a hazard communication program.
- 2. Use of the substances only as described in the consent order.
- 3. No use of the substances resulting in surface water concentrations exceeding 10 ppb of the aggregate of these PMN substances.

Recommended testing: EPA has determined that a daphnid chronic toxicity test (OPPTS Test Guidelines 850.1300) and a fish early life stage toxicity test (OPPTS Test Guidelines 850.1400) on either P-09-447 or P-09-448, would help characterize the environmental effects of the PMN substances. The order does not require the submission of these tests at any specified time or production volume. However, the order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10672.

PMN Numbers P-12-539, P-13-107, and P-13-109

Chemical names: Alkanes, C21-34 - branched and linear, chloro (P-12-539), Alkanes, C22-30 - branched and linear, chloro (P-13-107); and Alkanes, C24-28, chloro (P-13-109).

CAS numbers: 1417900-96-9 (P-12-539), 1401947-24-0 (P-13-107), and 1402738-52-6 (P-13-109).

Effective date of TSCA section 5(e) consent order: March 19, 2013.

Basis for TSCA section 5(e) consent order: The PMNs state that the uses of the substances are as flame retardants/plasticizers in polymers and extreme pressure lubricants in metal working fluids (MWFs). There are also several CBI uses that are generically described as: Plasticizer and lubricant with flame retardant properties. By analogy to medium chain chlorinated paraffins (MCCPs – alkyl chain length of 14 to 17), EPA expects very long chain chlorinated paraffins (vLCCPs) and possible degradation products to be potentially highly persistent, potentially bioaccumulative, and potentially toxic. Transport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans. EPA has concerns about the potential for the vLCCPs to degrade to shorter chain chlorinated compounds, as well as concerns about potential impurities or small fractions of MCCPs and/or long-chain chlorinated paraffins (LCCPs – alkyl chain length of 18 to 20). The consent order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to the environment and the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposures to the PMN substances. To protect against these risks, the consent order requires:

1. Manufacture or import of the substances at a cumulative, aggregate volume not to exceed 1,200,000 kilograms (kg), 14,100,000 kg, 59,100,000 kg, 78,400,000 kg, and 86,100,000 kg unless the company has submitted the results of certain environmental effects studies.

2. No manufacture of the substances with the amount of chlorinated paraffins with an alkyl chain ≤ 20 to exceed more than 1% of that PMN substance by weight. Recommended testing: EPA has determined that analysis for chain length and percent chlorination (for example by gas chromatography-mass spectrometry or high performance liquid chromatography-mass spectrometry (GC/MS HPLC/MS)); a modified semi-continuous activated sludge (SCAS) test (OPPTS Test Guideline 835.3210), modified SCAS test for insoluble and volatile chemicals (OPPTS Test Guideline 835.5045), or Zahn Wellens/EMPA test (OPPTS Test Guideline 835.3200); aerobic and anaerobic soil metabolism studies (Organisation for Economic Co-operation and Development (OECD) Test Guideline 307); a bioaccumulation in sediment-dwelling benthic oligochaetes test (OECD Test Guideline 315) on the PMN substances and their potential degradation products; and a sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment test (OECD Test Guideline 233) or a sedimentwater lumbriculus toxicity test using spiked sediment (OECD Test Guideline 225) on the PMN substances and their presumed degradation products would help characterize the effects of the PMN substances. Testing specifications are stated in the section 5(e) consent order for P-12-539, P-13-107, and P-13-109 available in the docket under docket ID number EPA-HQ-OPPT-2013-0399.

CFR citations: 40 CFR 721.10673 (P-12-539); 40 CFR 721.10674 (P-13-107); and 40 CFR 721.10675 (P-13-109).

PMN Number P-12-551

Chemical name: Aromatic hydrocarbon mixture (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as feedstock for fractionation process. Based on test data on the PMN substance and

ecological structural activity relationship (EcoSAR) analysis on analogous neutral

organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that

exceed 78 ppb of the PMN substance in surface waters. As described in the PMN,

releases of the substance are not expected to result in surface water concentrations that

exceed 78 ppb. Therefore, EPA has not determined that the proposed manufacturing,

processing, or use of the substance may present an unreasonable risk. EPA has

determined, however, that any use of the substance resulting in surface water

concentrations exceeding 78 ppb may cause significant adverse environmental effects.

Based on this information, the PMN substance meets the concern criteria at § 721.170

(b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a daphnid chronic toxicity

test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test

Guideline 850.1400), and an inherent biodegradability - Concawe test (OPPTS Test

Guidelines 835.3215) would help characterize the environmental effects of the PMN

substance. EPA also recommends that the guidance document on aquatic toxicity testing

of difficult substances and mixtures (OECD Test Guideline 23) be followed to facilitate

solubility in the test media, because of the PMN's low water solubility.

CFR citation: 40 CFR 721.10676.

PMN Number P-12-584

Chemical name: Alkyl phosphonate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an intermediate. Based on test data on an analog substance, EPA identified concerns for eye, lung, and mucous membrane irritation as well as kidney and developmental toxicity to workers exposed to the PMN substance. For the use described in the PMN, significant worker exposure is unlikely. Further, based on EcoSAR analysis of test data on analogous phosphinate esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as an intermediate, any use of the substance without the use of impervious gloves when there is potential dermal exposure, or any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause serious health effects and significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(ii) and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a combined repeated dose toxicity with the reproduction/development toxicity screening test (OPPTS Test Guideline 870.3650); an algal toxicity test (OCSPP Test Guideline 850.4500); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075) would help characterize the human health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10677.

PMN Number P-13-10

Chemical name: 1,4-Cyclohexanedicarboxylic acid, 1,4-dimethyl ester, hydrogenolysis

products.

CAS number: 1373220-73-5.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

is as a chemical intermediate. Based on EcoSAR analysis of test data on analogous esters,

EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 20

ppb of the PMN substance in surface waters. As described in the PMN, releases of the

PMN substance are not expected to result in surface water concentrations that exceed 20

ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or

use of the substance may present an unreasonable risk. EPA has determined, however,

that any use of the substance resulting in surface water concentrations exceeding 20 ppb

may cause significant adverse environmental effects. Based on this information, the PMN

substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that results of an aquatic invertebrate acute

toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); a fish acute toxicity

test, freshwater and marine (OPPTS Test Guideline 850.1075); and an algal toxicity test

(OCSPP Test Guideline 850.4500) would help characterize the environmental effects of

the PMN substance.

CFR citation: 40 CFR 721.10678.

PMN Number P-13-30

Chemical name: Carboxylic acid, substituted alkylstannylene ester, reaction products

with inorganic acid tetra alkyl ester (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

is as an adhesive/sealant component. Based on test data on the PMN substance, EPA

identified concerns for thymus toxicity to workers exposed to the PMN substance. As

described in the PMN, adequate dermal protection is used and worker exposure will be

minimal and there are no consumer exposures. Therefore, EPA has not determined that

the proposed manufacturing, processing, or use of the substance may present an

unreasonable risk. EPA has determined, however, that use of the substance in consumer

products or any use of the substance without the use of impervious gloves, when there is

potential dermal exposure, may result in significant adverse human health effects. Based

on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i).

Recommended testing: EPA has determined that the results of a skin absorption: In vivo

method test (OECD Test Guideline 427) would help characterize the human health

effects of the PMN substance.

CFR citation: 40 CFR 721.10679.

PMN Numbers P-13-44, P-13-46, P-13-47, P-13-50, and P-13-51

Chemical names: Fatty acid amides (generic).

CAS numbers: Not available.

Basis for action: The PMNs state that the use of the substances will be as adhesive

promoters for asphalt applications and emulsifiers for asphalt applications. Based on the

EcoSAR analysis of test data on analogous aliphatic amines and amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substances respectively in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substances to surface waters exceed releases from the uses described in the PMNs. For the use described in the PMNs, environmental releases did not exceed the respective concentrations of concern for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substances other than as an adhesive promoter for asphalt applications or as emulsifiers for asphalt applications, as described in the PMNs, could result in exposures which may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed. Testing may be performed on any one of the PMN substances (P-13-44, P-13-46, P-13-47, P-13-50, or P-13-51).

CFR citation: 40 CFR 721.10680.

PMN Numbers P-13-55 and P-13-56

Chemical names: Alkaneamide, halo-dialkylthienyl-alkoxydialkyl-, manuf. of by-

products from (generic).

CAS numbers: Not available.

Basis for action: The PMNs states that the generic (non-confidential) use of the

substances will be as starting material in sulfuric acid production. Based on EcoSAR

analysis of test data on analogous haloacetamides, EPA predicts toxicity to aquatic

organisms may occur at concentrations that exceed 1 ppb of the PMN substances in

surface waters. As described in the PMN, releases of the PMN substances are not

expected to result in surface water concentrations exceeding 1 ppb. Therefore, EPA has

not determined that the proposed manufacturing, processing, or use of these substances

may present an unreasonable risk. EPA has determined, however, that any use of these

substances other than as stated in the PMN or use of the substances resulting in releases

to surface water concentrations exceeding 1 ppb may cause significant adverse

environmental effects. Based on this information, the PMN substances meets the concern

criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of an algal toxicity test

(OCSPP Test Guideline 850.4500); an aquatic invertebrate acute toxicity test, freshwater

daphnids (OPPTS Test Guideline 850.1010); and a fish acute toxicity test, freshwater and

marine (OPPTS Test Guideline 850.1075) would help characterize the environmental

effects of the PMN substances.

CFR citation: 40 CFR 721.10681.

PMN Numbers P-13-63, P-13-64, P-13-65, P-13-69, P-13-70, P-13-71, P-13-72, P-13-73, P-13-74, P-13-75, P-13-76, and P-13-77

Chemical names: Fatty acid amide hydrochlorides (generic).

CAS numbers: Not available.

Basis for action: The PMNs state that the substances will be used as surfactants for asphalt emulsions. Based on the EcoSAR analysis of test data on analogous aliphatic amines and amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb (for P-13-63 P-13-64, P-13-65, P-13-69, P-13-70, P-13-71 P-13-72, P-13-73, and P-13-74) and 2 ppb (for P-13-75, P-13-76, and P-13-77) of the PMN substances respectively in surface waters for greater than 20 days per year. This 20day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substances to surface water exceed releases from the use described in the PMNs. For the use described in the PMNs, environmental releases did not exceed the respective concentrations of concern for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substances other than as surfactants for use in asphalt emulsions, as described in the PMNs, could result in exposures which may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute

toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed. Testing may be performed on any one of the PMN substances (P-13-63, P-13-64, P-13-65, P-13-69, P-13-70, P-13-71, P-13-72, P-13-73, P-13-74, P-13-75, P-13-76, or P-13-77).

CFR citation: 40 CFR 721.10682.

PMN Number P-13-131

Chemical name: Dialkylamino cocoalkyl alkylamide acid salt (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an inhibitor for oil field applications. Based on the EcoSAR analysis of test data on analogous amides and aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the PMN substance are not expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a ready biodegradability test (OECD Test Guideline 301B), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10683.

PMN Number P-13-135

Chemical name: Substituted benzenamine schiff base (generic).

CAS number: Not available.

Basis for action: The PMN states that the use of the substance is as an intermediate monomer for use in the manufacture of another monomer. Based on the EcoSAR analysis of test data on analogous schiff bases, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases of the PMN substance to surface waters are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of an algal toxicity test (OCSPP Test Guideline 850.4500); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); a fish early-stage toxicity test (OPPTS Test Guideline 850.1400); a partition coefficient (n-octanol/water), estimation by liquid chromatography test (OPPTS

Test Guideline 830.7570); a ready biodegradability test (OECD Test Guideline 301); and

a hydrolysis as a function of pH test (OPPTS Test Guideline 835.2120) would help

characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10684.

PMN Number P-13-170

Chemical name: Phosphoric acid, mixed esters (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

is as a plastic additive. Based on test data on the PMN substance, EPA predicts toxicity to

aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance

in surface waters. As described in the PMN, releases of the PMN substance are not

expected to result in surface water concentrations that exceed 1 ppb. Therefore, EPA has

not determined that the proposed manufacturing, processing, or use of the substance may

present an unreasonable risk. EPA has determined, however, that any use of the substance

resulting in surface water concentrations exceeding 1 ppb may cause significant adverse

environmental effects. Based on this information, the PMN substance meets the concern

criteria at § 721.170(b)(4)(i).

Recommended testing: EPA has determined that the results of a daphnid chronic toxicity

test (OPPTS Test Guideline 850.1300) and a fish early-life stage toxicity test (OPPTS

Test Guideline 850.1400) would help characterize the environmental effects of the PMN

substance. EPA also recommends that the guidance document on aquatic toxicity testing

of difficult substances and mixtures (OECD Test Guideline 23) be followed.

CFR citation: 40 CFR 721.10685.

PMN Numbers P-13-180, P-13-181, P-13-182, P-13-183, P-13-184, and P-13-185

Chemical names: Fatty acid amides (generic).

CAS numbers: Not available.

Basis for action: The PMNs state that the use of the substances is as adhesive promoters for asphalt applications and emulsifiers for asphalt applications. Based on the EcoSAR analysis of test data on analogous aliphatic amines and amides, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb (for P-13-180, P-13-182, and P-13-185); 2 ppb (for P-13-181 and P-13-183); and 4 ppb (for P-13-184) of the PMN substances in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substances to surface water exceed releases from the use described in the PMNs. For the use described in the PMNs, environmental releases did not exceed the respective concentrations of concern for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substances other than as adhesive promoters for asphalt applications or emulsifiers for asphalt applications, as described in the PMNs, could result in exposures which may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute

toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed. Testing may be performed on any one of the PMN substances (P-13-180, P-13-181, P-13-182, P-13-183, P-13-184, or P-13-185), however, it is recommended that it be conducted on P-13-182 as EPA predicts this substance to be most acutely toxic to aquatic organisms.

CFR citation: 40 CFR 721.10686.

PMN Numbers P-13-201, P-13-203, P-13-204, P-13-205, P-13-206, P-13-207, P-13-208, and P-13-209

Chemical names: Fatty acid amide hydrochlorides (generic).

CAS numbers: Not available.

Basis for action: The PMNs state that the use of the substances is as surfactants for asphalt emulsions. Based on the EcoSAR analysis of test data on analogous aliphatic amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb (for P-13-204, P-13-206, and P-13-207); 2 ppb (for P-13-205); 3 ppb (for P-13-209); 5 ppb (for P-13-201); 6 ppb (for P-13-208); and 12 ppb (for P-13-203) of the PMN substances respectively in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early-life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substances to surface waters exceed releases from the use described in the PMNs. For the use described in the PMNs,

environmental releases did not exceed the respective surface water concentrations for more than 20 days per year. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances other than as surfactants for asphalt emulsions could result in exposures which may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substances. EPA also recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed. Testing may be performed on any one of the PMN substances (P-13-201, P-13-203, P-13-204, P-13-205, P-13-206, P-13-207, P-13-208, or P-13-209). CFR citation: 40 CFR 721.10687.

PMN Number P-13-221

Chemical name: Copper, chloro[tris(2-chloroethyl) phosphite-.kappa.P]-.

CAS number: 24484-01-3.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a manufacturing process aid. Also, EPA identified concerns for oncogenicity, mutagenicity, and developmental toxicity based on the alkylation potential of the PMN substance and concern for neurotoxicity and reproductive toxicity based on analog test

data. There is also concern for immunotoxicity based on the presence of the copper ion. These concerns are for effects to workers from inhalation exposure to the PMN. Additionally, based on the EcoSAR analysis of test data on analogous organic copper compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 6 ppb of the PMN substance in surface waters. As described in the PMN, significant workplace exposures are not expected and releases of the PMN substance are not expected to result in surface water concentrations that exceed 6 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance other than as described in the PMN or any use of the substance resulting in surface water concentrations exceeding 6 ppb may cause serious health or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at $\S 721.170 (b)(1)(i)(C)$, (b)(3)(ii), and (b)(4)(ii). Recommended testing: EPA has determined that a carcinogenicity test (OPPTS Test Guideline 870.4200) in rats; an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); and an algal toxicity test (OCSPP Test

Guideline 850.4500) would help characterize the human health and environmental effects

of the PMN substance. EPA recommends that the guidance document on aquatic toxicity

testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.

CFR citation: 40 CFR 721.10688.

PMN Number P-13-225

Chemical name: Organo zinc salts (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a stabilizer for thermoplastics. Based on the EcoSAR analysis of test data on analogous organic zinc compounds, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb of the PMN substance in surface waters. As described in the PMN, releases of the substance are not expected to result in surface water concentrations that exceed 3 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 3 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300), a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400), and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10689.

PMN Number P-13-232

Chemical name: Benzenedicarboxylic acid, polymer with substituted alkanediol, dodecanedioic acid, 1,2-ethanediol, alkanedioic acid, alkanediol, alpha.-hydro-.omega.-hydroxypoly[oxyalkanediyl], 1,3-isobenzofurandione, methylene diphenyl diisocyanate, 2-oxepanone, 2,2'-oxybis[ethanol] and polymethylene polyphenylene isocyanate (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

will be as an industrial adhesive. Based on analogous diisocyanates, EPA identified

concerns for sensitization as well as lung and mucous membrane irritation. For the use

described in the PMN, EPA does not expect significant occupational or consumer

inhalation exposure as the substance is not applied using a method that generates a vapor,

mist, or aerosol or used in a consumer product. Therefore, EPA has not determined that

the proposed manufacturing, processing, or use of the substance may present an

unreasonable risk. EPA has determined, however, that any use of the substance in

consumer products or any use of the substance involving an application method that

generates a vapor, mist, or aerosol may cause serious health effects. Based on this

information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test

(OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test

Guideline 870.3465) would help characterize the human health effects of the PMN

substance.

CFR citation: 40 CFR 721.10690.

PMN Number P-13-267

Chemical name: Fatty acid amide (generic).

CAS number: Not available.

Basis for action: The PMN states that the use of the substance is as a polymer additive.

Based on the EcoSAR analysis of test data on analogous amides, EPA predicts toxicity to

aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance

in surface waters. As described in the PMN, releases of the PMN substance to surface waters are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that an algal toxicity test (OCSPP Test Guideline 850.4500), a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and the shake flask die-away test (OPPTS Test Guideline 835.3170) would help characterize the environmental effects of the PMN substance. EPA recommends that the guidance document on aquatic toxicity testing of difficult substances and mixtures (OECD Test Guideline 23) be followed.

CFR citation: 40 CFR 721.10691.

PMN Number P-13-288

Chemical name: Fluorinated alkyl dianiline (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as a polymer precursor. EPA identified concern for acute toxicity based on test data on the PMN substance. Also, EPA identified concern for dermal sensitization and oncogenicity based on benzidines; concern for neurotoxicity based on aromatic amines; and concern for retinopathy based on dianiline compounds. The concern is for workers

exposed to the PMN substance. For the industrial use described in the PMN, significant worker dermal or inhalation exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the PMN substance other than as an intermediate may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C), (b)(3)(i), and (b)(3)(ii).

Recommended testing: EPA has determined that the results of a rat acute oral retinopathy screening study (protocol to be approved by EPA to include histopathological examination of the eyes by both light and electron microscopy) would help characterize the health effects of the PMN substance.

CFR citation: 40 CFR 721.10692.

PMN Number P-13-338

Chemical name: Diphenylmethane diisocyanate polymer with alkanoic diacid and alkanediol (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a polymer intermediate for adhesive manufacture. Based on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization, irritation, and lung effects. For the use described in the PMN, EPA does not expect significant occupational or consumer inhalation exposure as the substance is not applied using a method that generates a vapor, mist, or aerosol or used in a consumer product. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the

substance may present an unreasonable risk. EPA has determined, however, that any use of the substance in consumer products or any use of the substance involving an application method that generates a vapor, mist, or aerosol may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10693.

V. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for 7 of the 53 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit VI.).

In the other 46 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at

§ 721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA will ensure that all manufacturers and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory).

Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is [insert date 60 days after date of publication in the Federal Register] without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before [insert date 30 days after date of publication in the Federal Register].

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [insert date 30 days after date of publication in the Federal Register], EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies.

EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

VII. Applicability of the Significant New Use Designation

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical

substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA section 5(e) consent orders have been issued for 7 of the 53 chemical substances, and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which would be designated as significant new uses. The identities of 5 of the 53 chemical substances subject to this rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

Therefore EPA designates [insert date of publication in the Federal Register] as the cutoff date for determining whether the new use is ongoing. Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the Federal Register document of April 24, 1990 for a more detailed discussion of the cutoff date for ongoing uses.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

- 1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
- 2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-section 5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to http://www.epa.gov/ocspp and select "Test Methods and Guidelines." The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at http://www.oecdbookshop.org or SourceOECD at http://www.sourceoecd.org.

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this rule, EPA has established production volume limits in view of the

lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

• Human exposure and environmental release that may result from the significant new use of the chemical substances.

- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1).

Under these procedures a manufacturer or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a

significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 720.40 and 721.25. E-PMN software is available electronically at http://www.epa.gov/opptintr/newchems.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2013-0399.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

This rule establishes SNURs for several new chemical substances that were the subject of PMNs, or TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 et seq.), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

- 1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- 2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this rule.

This rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit XI. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rule. As such, EPA has determined that this rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

XIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

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List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 30, 2013.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9--[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following sections in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation				OMB control No.	
*	*	*	*	*	
Significant New Uses of Chemical Substances					
*	*	*	*	*	
721.10671			2070-0012		
721.10672			2070-0012		
721.10673			2070-0012		
721.10674			2070-0012		
721.10675			2070-0012		
721.10676			2070-0012		

721.10677	2070-0012
721.10678	2070-0012
721.10679	2070-0012
721.10680	2070-0012
721.10681	2070-0012
721.10682	2070-0012
721.10683	2070-0012
721.10684	2070-0012
721.10685	2070-0012
721.10686	2070-0012
721.10687	2070-0012
721.10688	2070-0012
721.10689	2070-0012
721.10690	2070-0012
721.10691	2070-0012
721.10692	2070-0012
721.10693	2070-0012
* * *	* *

* * * * *

PART 721--[AMENDED]

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

4. Add \S 721.10671 to subpart E to read as follows:

§ 721.10671 Multi-walled carbon nanotubes (generic).

- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substances identified generically as multi-walled carbon nanotubes (PMNs P-09-198 and P-09-199) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); embedded or incorporated into a polymer matrix that itself has been reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing, except mechanical processing.
 - (2) The significant new uses are:
- (i) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4) (National Institute of Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters), (a)(6)(i), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (f), (k), and (q).
 - (iii) Release to water. Requirements as specified in § 721.90 (b)(1) and (c)(1).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers and processors of these substances.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.
 - 5. Add § 721.10672 to subpart E to read as follows:

§ 721.10672 Sodium olefin sulfonate derivative (generic).

- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substances identified generically as sodium olefin sulfonate derivative (PMNs P-09-447 and P-09-448) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the chemical substances after they have been completely reacted (cured) or partitioned into oil or petroleum streams following use as specific enhanced oil recovery applications that have been claimed confidential.
 - (2) The significant new uses are:
- (i) *Hazard communication program*. Requirements as specified in § 721.72 (a), (b), (c). (d), (e) (concentration set at 1.0 percent), (f), (g)(3)(i), (g)(3)(ii), (g)(4)(i), and (g)(5).
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(k).

- (iii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=10).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (f), (g), (h), (i), and (k) are applicable to manufacturers and processors of these substances.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(1) of this section.
 - 6. Add § 721.10673 to subpart E to read as follows:

§ 721.10673 Alkanes, C21-34 - branched and linear, chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes, C21-34 branched and linear, chloro (PMN P-12-539; CAS No. 1417900-96-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use is manufacture of the PMN substance with greater than 1 weight percent ("wt%") of chlorinated ("Cl") paraffins with an alkyl chain ≤ 20 and § 721.80(r) (Testing phase 1 is reached at 1,200,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes analysis for chain length

and percent chlorination (for example by gas chromatography-mass spectrometry or high performance liquid chromatography-mass spectrometry). Present EPA with a certificate of analysis and all raw data for congener analysis on P-12-539, P-13-107, and P-13-109. Testing phase 2a is reached at 14,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes a modified semi-continuous activated sludge (SCAS) test or modified SCAS test for insoluble and volatile chemicals or Zahn Wellens test with analytical procedures capable of measuring individual congeners and degradation products over time on three chlorinated linear C21 paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated C26 linear paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated linear paraffin fractions, whose chain length represents the central tendency of the congener distribution of the very long chain chlorinated paraffins (vLCCP) product as identified in testing phase 1, to represent each of the 40%, 55%, and > 70% chlorine by weight. Testing phase 2b is reached at 59,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes aerobic and anaerobic transformation in soil test with analytical procedures capable of measuring individual congeners and degradation products over time and bioaccumulation in sediment-dwelling benthic oligochaetes on three chlorinated linear C21 paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated C26 linear paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated linear paraffin fractions, whose chain length represents the central tendency of the congener distribution of the vLCCP product as identified in testing phase 1, to represent each of the 40%, 55%, and > 70% chlorine by weight.

Testing phase 3 is reached at 78,400,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. If the degradation half-life of the test substance is 28 days or shorter from testing phase 2a the sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment is an acceptable test, otherwise sediment-water lumbriculus toxicity test using spiked sediment is an acceptable test for any of the parent substances that are absorbed by the benthic oligochaetes in the bioaccumulation in sediment-dwelling benthic oligochaetes test. In the bioaccumulation in sediment-dwelling benthic oligochaetes test, use as test material any of the degradation products in testing phases 2a or 2b that are identified to potentially present an unreasonable risk or to further degrade to generate a substance of potential concern. Testing phase 4 is reached at 86,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. If the degradation half-life of the test substance is 28 days or shorter from testing phase 3 the sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment is an acceptable test, otherwise the sediment-water lumbriculus toxicity test using spiked sediment is an acceptable test. Use degradation substances in testing phase 3 that are absorbed by the benthic oligochaetes as the test material.)

- (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

7. Add § 721.10674 to subpart E to read as follows:

§ 721.10674 Alkanes, C22-30 - branched and linear, chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes, C22-30 branched and linear, chloro (PMN P-13-107; CAS No. 1401947-24-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80. A significant new use is manufacture of the PMN substance with greater than 1 weight percent ("wt%") of chlorinated ("Cl") paraffins with an alkyl chain ≤ 20 and § 721.80(r) (Testing phase 1 is reached at 1,200,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes analysis for chain length and percent chlorination (for example by gas chromatography-mass spectrometry or high performance liquid chromatography-mass spectrometry). Present EPA with a certificate of analysis and all raw data for congener analysis on P-12-539, P-13-107, and P-13-109. Testing phase 2a is reached at 14,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes a modified semi-continuous activated sludge (SCAS) test or modified SCAS test for insoluble and volatile chemicals or Zahn Wellens test with analytical procedures capable of measuring individual congeners and degradation products over time on three chlorinated linear C21 paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated C26 linear paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated linear paraffin fractions, whose chain length represents the

central tendency of the congener distribution of the very long chain chlorinated paraffins (vLCCP) product as identified in testing phase 1, to represent each of the 40%, 55%, and > 70% chlorine by weight. Testing phase 2b is reached at 59,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes aerobic and anaerobic transformation in soil test with analytical procedures capable of measuring individual congeners and degradation products over time and bioaccumulation in sediment-dwelling benthic oligochaetes on three chlorinated linear C21 paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated C26 linear paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated linear paraffin fractions, whose chain length represents the central tendency of the congener distribution of the vLCCP product as identified in testing phase 1, to represent each of the 40%, 55%, and > 70% chlorine by weight. Testing phase 3 is reached at 78,400,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. If the degradation half-life of the test substance is 28 days or shorter from testing phase 2a the sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment is an acceptable test, otherwise sediment-water lumbriculus toxicity test using spiked sediment is an acceptable test for any of the parent substances that are absorbed by the benthic oligochaetes in the bioaccumulation in sediment-dwelling benthic oligochaetes test. In the bioaccumulation in sediment-dwelling benthic oligochaetes test, use as test material any of the degradation products in testing phases 2a or 2b that are identified to potentially present an unreasonable risk or to further degrade to generate a substance of potential concern. Testing phase 4 is reached at 86,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13109. If the degradation half-life of the test substance is 28 days or shorter from testing phase 3 the sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment is an acceptable test, otherwise the sediment-water lumbriculus toxicity test using spiked sediment is an acceptable test. Use degradation substances in testing phase 3 that are absorbed by the benthic oligochaetes as the test material.)

- (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 8. Add § 721.10675 to subpart E to read as follows:

§ 721.10675 Alkanes, C24-28, chloro.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as alkanes, C24-28, chloro (PMN P-13-109; CAS No. 1402738-52-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use is manufacture of the PMN substance with greater than 1 weight percent ("wt%") of chlorinated ("Cl") paraffins with an alkyl chain ≤ 20 and

§ 721.80(r) (Testing phase 1 is reached at 1,200,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes analysis for chain length and percent chlorination (for example by gas chromatography-mass spectrometry or high performance liquid chromatography-mass spectrometry). Present EPA with a certificate of analysis and all raw data for congener analysis on P-12-539, P-13-107, and P-13-109. Testing phase 2a is reached at 14,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes a modified semi-continuous activated sludge (SCAS) test or modified SCAS test for insoluble and volatile chemicals or Zahn Wellens test with analytical procedures capable of measuring individual congeners and degradation products over time on three chlorinated linear C21 paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated C26 linear paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated linear paraffin fractions, whose chain length represents the central tendency of the congener distribution of the very long chain chlorinated paraffins (vLCCP) product as identified in testing phase 1, to represent each of the 40%, 55%, and > 70% chlorine by weight. Testing phase 2b is reached at 59,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. Testing includes aerobic and anaerobic transformation in soil test with analytical procedures capable of measuring individual congeners and degradation products over time and bioaccumulation in sediment-dwelling benthic oligochaetes on three chlorinated linear C21 paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated C26 linear paraffin fractions to represent each of the 40%, 55%, and > 70% chlorine by weight, three chlorinated linear paraffin fractions, whose chain length represents the

central tendency of the congener distribution of the vLCCP product as identified in testing phase 1, to represent each of the 40%, 55%, and > 70% chlorine by weight. Testing phase 3 is reached at 78,400,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. If the degradation half-life of the test substance is 28 days or shorter from testing phase 2a the sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment is an acceptable test, otherwise sediment-water lumbriculus toxicity test using spiked sediment is an acceptable test for any of the parent substances that are absorbed by the benthic oligochaetes in the bioaccumulation in sediment-dwelling benthic oligochaetes test. In the bioaccumulation in sediment-dwelling benthic oligochaetes test, use as test material any of the degradation products in testing phases 2a or 2b that are identified to potentially present an unreasonable risk or to further degrade to generate a substance of potential concern. Testing phase 4 is reached at 86,100,000 kg for the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109. If the degradation half-life of the test substance is 28 days or shorter from testing phase 3 the sediment-water chironomid life-cycle toxicity test using spiked water or spiked sediment is an acceptable test, otherwise the sediment-water lumbriculus toxicity test using spiked sediment is an acceptable test. Use degradation substances in testing phase 3 that are absorbed by the benthic oligochaetes as the test material.)

- (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers and processors of this substance.

- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 9. Add § 721.10676 to subpart E to read as follows:

§ 721.10676 Aromatic hydrocarbon mixture (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as aromatic hydrocarbon mixture (PMN P-12-551) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=78).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 10. Add § 721.10677 to subpart E to read as follows:

§ 721.10677 Alkyl phosphonate (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkyl phosphonate (PMN P-12-584) is

subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(g).
- (ii) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(1), (a)(2)(i), and (a)(3). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.
- (iii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), (d), (e), (i), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 11. Add § 721.10678 to subpart E to read as follows:

§ 721.10678 1,4-Cyclohexanedicarboxylic acid, 1,4-dimethyl ester, hydrogenolysis products.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1,4-cyclohexanedicarboxylic acid, 1,4-dimethyl ester,

hydrogenolysis products (PMN P-13-10; CAS No. 1373220-73-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=20).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 12. Add § 721.10679 to subpart E to read as follows:

§ 721.10679 Carboxylic acid, substituted alkylstannylene ester, reaction products with inorganic acid tetra alkyl ester (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as carboxylic acid, substituted alkylstannylene ester, reaction products with inorganic acid tetra alkyl ester (PMN P-13-30) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(o).

- (ii) *Protection in the workplace*. Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (b) (concentration set at 1.0%), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), (d), and (e) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 13. Add § 721.10680 to subpart E to read as follows:

§ 721.10680 Fatty acid amides (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as fatty acid amides (PMNs P-13-44, P-13-46, P-13-47, P-13-50, and P-13-51) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use is any use other than as adhesion promoters for asphalt applications or emulsifiers for asphalt applications.
 - (ii) [Reserved]

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 14. Add § 721.10681 to subpart E to read as follows:

§ 721.10681 Alkaneamide, halo-dialkylthienyl-alkoxydialkyl-, manuf. of by-products from (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as alkaneamide, halo-dialkylthienylalkoxydialkyl-, manuf. of by-products from (PMNs P-13-55 and PMN P-13-56) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j).
- (ii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (i) and (k) are applicable to manufacturers and processors of these substances.

- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 15. Add § 721.10682 to subpart E to read as follows:

§ 721.10682 Fatty acid amide hydrochlorides (generic).

- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substances identified generically as fatty acid amide hydrochlorides (PMNs P-13-63, P-13-64, P-13-65, P-13-69, P-13-70, P-13-71, P-13-72, P-13-73, P-13-74, P-13-75, P-13-76, and P-13-77) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use is any use other than as surfactants for use in asphalt emulsions.
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers and processors of these substances.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 16. Add § 721.10683 to subpart E to read as follows:

§ 721.10683 Dialkylamino cocoalkyl alkylamide acid salt (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as dialkylamino cocoalkyl alkylamide acid salt (PMN P-13-131) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.
 - 17. Add § 721.10684 to subpart E to read as follows:

§ 721.10684 Substituted benzenamine schiff base (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as substituted benzenamine schiff base (PMN P-13-135) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 18. Add § 721.10685 to subpart E to read as follows:

§ 721.10685 Phosphoric acid, mixed esters (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as phosphoric acid, mixed esters (PMN P-13-170) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers and processors of this substance.

- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 19. Add § 721.10686 to subpart E to read as follows:

§ 721.10686 Fatty acid amides (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as fatty acid amides (PMNs P-13-180, P-13-181, P-13-182, P-13-183, P-13-184, and P-13-185) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use is any use other than as adhesion promoters for asphalt applications or emulsifiers for asphalt applications.
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers and processors of these substances.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 20. Add § 721.10687 to subpart E to read as follows:

§ 721.10687 Fatty acid amide hydrochlorides (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substances identified generically as fatty acid amide hydrochlorides (PMNs P-

13-201, P-13-203, P-13-204, P-13-205, P-13-206, P-13-207, P-13-208, and P-13-209) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use is any use other than as surfactants for asphalt emulsions.
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers and processors of these substances.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 21. Add § 721.10688 to subpart E to read as follows:

§ 721.10688 Copper, chloro[tris(2-chloroethyl) phosphite-.kappa.P]-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as copper, chloro[tris(2-chloroethyl) phosphite-.kappa.P]-(PMN P-13-221; CAS No. 24484-01-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j).

- (ii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=6).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), (i), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 22. Add § 721.10689 to subpart E to read as follows:

§ 721.10689 Organo zinc salts (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as organo zinc salts (PMN P-13-225) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) Release to water. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=3).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 23. Add § 721.10690 to subpart E to read as follows:
- § 721.10690 Benzenedicarboxylic acid, polymer with substituted alkanediol, dodecanedioic acid, 1,2-ethanediol, alkanedioic acid, alkanediol, alpha.-hydro-.omega.-hydroxypoly[oxyalkanediyl], 1,3-isobenzofurandione, methylene diphenyl diisocyanate, 2-oxepanone, 2,2'-oxybis[ethanol] and polymethylene polyphenylene isocyanate (generic).
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as benzenedicarboxylic acid, polymer with substituted alkanediol, dodecanedioic acid, 1,2-ethanediol, alkanedioic acid, alkanediol, alpha.-hydro-.omega.-hydroxypoly[oxyalkanediyl], 1,3-isobenzofurandione, methylene diphenyl diisocyanate, 2-oxepanone, 2,2'-oxybis[ethanol] and polymethylene polyphenylene isocyanate (PMN P-13-232) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (o) and (y)(1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers and processors of this substance.

- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 24. Add § 721.10691 to subpart E to read as follows:

§ 721.10691 Fatty acid amide (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as fatty acid amide (PMN P-13-267) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.
 - 25. Add § 721.10692 to subpart E to read as follows:

§ 721.10692 Fluorinated alkyl dianiline (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as fluorinated alkyl dianiline (PMN P-13-288)

is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(g).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 26. Add § 721.10693 to subpart E to read as follows:

§ 721.10693 Diphenylmethane diisocyanate polymer with alkanoic diacid and alkanediol (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as diphenylmethane diisocyanate polymer with alkanoic diacid and alkanediol (PMN P-13-338) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (o) and (y)(1).
 - (ii) [Reserved]

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(b) Specific requirements. The provisions of subpart A of this part apply to this

section except as modified by this paragraph.

(1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),

(c), and (i) are applicable to manufacturers and processors of this substance.

(2) Limitations or revocation of certain notification requirements. The provisions

of § 721.185 apply to this section.

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